As Reported by the House Health Committee

132nd General Assembly

Regular Session 2017-2018

Sub. S. B. No. 119

Senators Hackett, Hottinger

Cosponsors: Senators Beagle, Balderson, Brown, Burke, Dolan, Eklund, Gardner, Hoagland, Kunze, LaRose, Lehner, Manning, O'Brien, Oelslager, Peterson, Schiavoni, Terhar, Uecker, Wilson Representatives Gavarone, Antani, Butler, Duffey, Edwards, Ginter, Johnson, Lepore-Hagan

A BILL

То	amend sections 4723.52, 4729.01, 4729.44,	1
	4729.75, 4729.79, 4729.85, 4730.56, 4731.83, and	2
	5119.363, to amend, for the purpose of adopting	3
	a new section number as indicated in	4
	parentheses, section 3715.08 (3719.064), and to	-
	enact sections 3719.063, 4729.283, and 4765.45	6
	of the Revised Code regarding naloxone,	7
	naltrexone, and medication-assisted treatment.	8

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 4723.52, 4729.01, 4729.44,	9
4729.75, 4729.79, 4729.85, 4730.56, 4731.83, and 5119.363 be	10
amended, section 3715.08 (3719.064) be amended for the purpose	11
of adopting a new section number as indicated in parentheses,	12
and sections 3719.063, 4729.283, and 4765.45 of the Revised Code	13
be enacted to read as follows:	14
Sec. 3719.063. In the absence of gross negligence or	15
intentional misconduct, a person who administers the drug	16

drug if all of the following conditions are met:	21
(A) The individual to whom the drug is administered is	22
unable to have it administered as follows:	23
(1) By a person who routinely administers the drug to the	24
individual;	25
(2) At the facility at which the drug is routinely	26
administered to the individual;	27
(3) Under the direction of the drug's prescriber.	28
(B) The person who administers the drug under this section	29
is legally authorized to administer it by injection but is not	30
the prescriber of the drug or one who routinely administers it	31
to the individual.	32
(C) The drug is provided to the person who administers it	33
under this section in either of the following ways:	34
(1) By the individual to whom it is administered;	35
(2) By the pharmacy that has a record of a prescription	36
for the drug in the name of the individual to whom it is	37
administered.	38
(D) The person who administers the drug under this section	39
is authorized to do so by that person's employer or the facility	40
at which the drug is administered.	41
Sec. 3715.08 3719.064. (A) As used in this section:	42
(1) "Medication-assisted treatment" has the same meaning	43

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treatment is clinically appropriate and meets generally accepted	73
standards of medicine, the prescriber shall refer the patient to	74
a qualifying practitioner. If the patient's choice is methadone	75
treatment and the prescriber determines that such treatment is	76
clinically appropriate and meets generally accepted standards of	77
medicine, the prescriber shall refer the patient to a community	78
addiction services provider licensed under section 5119.391 of	79
the Revised Code. In either case, the prescriber or the	80
prescriber's delegate shall make a notation in the patient's	81
medical record naming the practitioner or provider to whom the	82
patient was referred and specifying when the referral was made.	83
Sec. 4723.52. (A) As used in this section:	84
(1) "Community addiction services provider" has the same	85
meaning as in section 5119.01 of the Revised Code.	86
(2) "Medication-assisted treatment" has the same meaning	87
as in section 340.01 of the Revised Code.	88
(B) An advanced practice registered nurse shall comply	89
with section $\frac{3715.08}{3719.064}$ of the Revised Code and rules	90
adopted under section 4723.51 of the Revised Code when treating	91
a patient for addiction with medication-assisted treatment or	92
proposing to initiate such treatment.	93
(C) An advanced practice registered nurse who fails to	94
comply with this section shall treat not more than thirty	95
patients at any one time with medication-assisted treatment even	96
if the facility or location at which the treatment is provided	97
is either of the following:	98
(1) Exempted by divisions (B)(2)(a) to (d) of section	99
4729.553 of the Revised Code from being required to possess a	100

category III terminal distributor of dangerous drugs license

(5) Pursuant to a request made by a licensed health	156
professional authorized to prescribe drugs for a drug that is to	157
be used by the professional for the purpose of direct	158
administration to patients in the course of the professional's	159
practice, if all of the following apply:	160
(a) At the time the request is made, the drug is not	161
commercially available regardless of the reason that the drug is	162
not available, including the absence of a manufacturer for the	163
drug or the lack of a readily available supply of the drug from	164
a manufacturer.	165
(b) A limited quantity of the drug is compounded and	166
provided to the professional.	167
(c) The drug is compounded and provided to the	168
professional as an occasional exception to the normal practice	169
of dispensing drugs pursuant to patient-specific prescriptions.	170
(D) "Consult agreement" means an agreement that has been	171
entered into under section 4729.39 of the Revised Code.	172
(E) "Drug" means:	173
(1) Any article recognized in the United States	174
pharmacopoeia and national formulary, or any supplement to them,	175
intended for use in the diagnosis, cure, mitigation, treatment,	176
or prevention of disease in humans or animals;	177
(2) Any other article intended for use in the diagnosis,	178
cure, mitigation, treatment, or prevention of disease in humans	179
or animals;	180
(3) Any article, other than food, intended to affect the	181
structure or any function of the body of humans or animals;	182
(4) Any article intended for use as a component of any	183

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written, electronic, or oral order for an epinephrine	240
autoinjector issued to and in the name of a qualified entity, as	241
defined in section 3728.01 of the Revised Code.	242
(I) "Licensed health professional authorized to prescribe	243
drugs" or "prescriber" means an individual who is authorized by	244
law to prescribe drugs or dangerous drugs or drug therapy	245
related devices in the course of the individual's professional	246
practice, including only the following:	247
(1) A dentist licensed under Chapter 4715. of the Revised	248
Code;	249
(2) A clinical nurse specialist, certified nurse-midwife,	250
or certified nurse practitioner who holds a current, valid	251
license to practice nursing as an advanced practice registered	252
nurse issued under Chapter 4723. of the Revised Code;	253
(3) An optometrist licensed under Chapter 4725. of the	254
Revised Code to practice optometry under a therapeutic	255
pharmaceutical agents certificate;	256
(4) A physician authorized under Chapter 4731. of the	257
Revised Code to practice medicine and surgery, osteopathic	258
medicine and surgery, or podiatric medicine and surgery;	259
(5) A physician assistant who holds a license to practice	260
as a physician assistant issued under Chapter 4730. of the	261
Revised Code, holds a valid prescriber number issued by the	262
state medical board, and has been granted physician-delegated	263
prescriptive authority;	264
(6) A veterinarian licensed under Chapter 4741. of the	265
Revised Code.	266
(J) "Sale" or "sell" includes any transaction made by any	267

person, whether as principal proprietor, agent, or employee, to	268
do or offer to do any of the following: deliver, distribute,	269
broker, exchange, gift or otherwise give away, or transfer,	270
whether the transfer is by passage of title, physical movement,	271
or both.	272
(K) "Wholesale sale" and "sale at wholesale" mean any sale	273
in which the purpose of the purchaser is to resell the article	274
purchased or received by the purchaser.	275
(L) "Retail sale" and "sale at retail" mean any sale other	276
than a wholesale sale or sale at wholesale.	277
(M) "Retail seller" means any person that sells any	278
dangerous drug to consumers without assuming control over and	279
responsibility for its administration. Mere advice or	280
instructions regarding administration do not constitute control	281
or establish responsibility.	282
(N) "Price information" means the price charged for a	283
prescription for a particular drug product and, in an easily	284
understandable manner, all of the following:	285
(1) The proprietary name of the drug product;	286
(2) The established (generic) name of the drug product;	287
(3) The strength of the drug product if the product	288
contains a single active ingredient or if the drug product	289
contains more than one active ingredient and a relevant strength	290
can be associated with the product without indicating each	291
active ingredient. The established name and quantity of each	292
active ingredient are required if such a relevant strength	293
cannot be so associated with a drug product containing more than	294
one ingredient.	295

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(4) The dosage form;	296
(5) The price charged for a specific quantity of the drug	297
product. The stated price shall include all charges to the	298
consumer, including, but not limited to, the cost of the drug	299
product, professional fees, handling fees, if any, and a	300
statement identifying professional services routinely furnished	301
by the pharmacy. Any mailing fees and delivery fees may be	302
stated separately without repetition. The information shall not	303
be false or misleading.	304
(O) "Wholesale distributor of dangerous drugs" or	305
"wholesale distributor" means a person engaged in the sale of	306
dangerous drugs at wholesale and includes any agent or employee	307
of such a person authorized by the person to engage in the sale	308
of dangerous drugs at wholesale.	309
(P) "Manufacturer of dangerous drugs" or "manufacturer"	310
means a person, other than a pharmacist or prescriber, who	311
manufactures dangerous drugs and who is engaged in the sale of	312
those dangerous drugs.	313
(Q) "Terminal distributor of dangerous drugs" or "terminal	314
distributor" means a person who is engaged in the sale of	315
dangerous drugs at retail, or any person, other than a	316
manufacturer, repackager, outsourcing facility, third-party	317
logistics provider, wholesale distributor, or pharmacist, who	318
has possession, custody, or control of dangerous drugs for any	319
purpose other than for that person's own use and consumption.	320
"Terminal distributor" includes pharmacies, hospitals, nursing	321
homes, and laboratories and all other persons who procure	322

dangerous drugs for sale or other distribution by or under the

supervision of a pharmacist or licensed health professional

authorized to prescribe drugs.

(R) "Promote to the public" means disseminating a	326
representation to the public in any manner or by any means,	327
other than by labeling, for the purpose of inducing, or that is	328
likely to induce, directly or indirectly, the purchase of a	329
dangerous drug at retail.	330
(S) "Person" includes any individual, partnership,	331
association, limited liability company, or corporation, the	332
state, any political subdivision of the state, and any district,	333
department, or agency of the state or its political	334
subdivisions.	335
(T) "Animal shelter" means a facility operated by a humane	336
society or any society organized under Chapter 1717. of the	337
Revised Code or a dog pound operated pursuant to Chapter 955. of	338
the Revised Code.	339
(U) "Food" has the same meaning as in section 3715.01 of	340
the Revised Code.	341
(V) "Pain management clinic" has the same meaning as in	342
section 4731.054 of the Revised Code.	343
(W) "Investigational drug or product" means a drug or	344
product that has successfully completed phase one of the United	345
States food and drug administration clinical trials and remains	346
under clinical trial, but has not been approved for general use	347
by the United States food and drug administration.	348
"Investigational drug or product" does not include controlled	349
substances in schedule I, as established pursuant to section	350
3719.41 of the Revised Code, and as amended.	351
(X) "Product," when used in reference to an	352
investigational drug or product, means a biological product,	353
other than a drug, that is made from a natural human, animal, or	354

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(3) In the exercise of the pharmacist's professional	384
<pre>judgment:</pre>	385
(a) The drug is necessary to continue the patient's	386
therapy for substance use disorder.	387
(b) Failure to dispense the drug to the patient could	388
result in harm to the health of the patient.	389
(B) Before dispensing naltrexone under this section, the	390
pharmacist shall offer the patient the choice of receiving	391
either the oral form or injectable long-acting or extended-	392
release form, but only if both forms of the drug are available	393
for dispensing at the time of the patient's request or within	394
one day after the request.	395
(C) (1) With respect to naltrexone dispensed in an oral	396
form under this section, the pharmacist shall not dispense an	397
amount that exceeds a five-day supply.	398
(2) With respect to naltrexone dispensed in an injectable	399
long-acting or extended-release form under this section, both of	400
the following apply:	401
(a) The pharmacist shall exercise professional judgment in	402
determining the amount of the drug dispensed.	403
(b) The pharmacist may administer the drug by injection to	404
the patient but only in accordance with section 4729.45 of the	405
Revised Code.	406
(D) A pharmacist who dispenses naltrexone under this	407
section shall do all of the following:	408
(1) For one year after the date of dispensing, maintain a	409
record in accordance with this chapter of the drug dispensed,	410
including the amount and form dispensed, the original	411

prescription number, the name and address of the patient and, if	412
the individual receiving the drug is not the patient, the name	413
and address of that individual;	414
(2) Notify the prescriber who issued the prescription	415
described in division (A)(1) of this section or another	416
prescriber responsible for the patient's care not later than	417
five days after the drug is dispensed;	418
(3) If applicable, obtain authorization for additional	419
dispensing from one of the prescribers described in division (D)	420
(2) of this section.	421
(E) A pharmacist shall exercise professional judgment in	422
determining the number of times naltrexone may be dispensed	423
under this section to the same patient.	424
(F) This section does not limit the authority of a	425
pharmacist to dispense a dangerous drug under section 4729.281	426
of the Revised Code.	427
Sec. 4729.44. (A) As used in this section:	428
(1) "Board of health" means a board of health of a city or	429
general health district or an authority having the duties of a	430
board of health under section 3709.05 of the Revised Code.	431
(2) "Physician" means an individual authorized under	432
Chapter 4731. of the Revised Code to practice medicine and	433
surgery, osteopathic medicine and surgery, or podiatric medicine	434
and surgery.	435
(B) If use of the protocol developed pursuant to rules	436
adopted under division (G) of this section has been authorized	437
under section 3707.56 or 4731.942 of the Revised Code, a	438
pharmacist or pharmacy intern may dispense naloxone without a	439

prescription to either of the following in accordance with that	440
<pre>protocol:</pre>	441
(1) An individual who there is reason to believe is	442
experiencing or at risk of experiencing an opioid-related	443
overdose;	444
(2) A family member, friend, or other person individual in	445
a position to assist an individual who there is reason to	446
believe is at risk of experiencing an opioid-related overdose.	447
(C) A pharmacist or pharmacy intern who dispenses naloxone	448
under this section shall instruct the individual to whom	449
naloxone is dispensed to summon emergency services as soon as	450
practicable either before or after administering naloxone.	451
(D) A pharmacist may document on a prescription form the	452
dispensing of naloxone by the pharmacist or a pharmacy intern	453
supervised by the pharmacist on a prescription form . The form	454
may be assigned a number for record-keeping purposes.	455
(E) This section does not affect the authority of a	456
pharmacist or pharmacy intern to fill or refill a prescription	457
for naloxone.	458
(F) A board of health that in good faith authorizes a	459
pharmacist or pharmacy intern to dispense naloxone without a	460
prescription in accordance with a protocol developed pursuant to	461
rules adopted under division (G) of this section is not liable	462
for or subject to any of the following for any action or	463
omission of the individual to whom the naloxone is dispensed:	464
damages in any civil action, prosecution in any criminal	465
proceeding, or professional disciplinary action.	466
A physician who in good faith authorizes a pharmacist or	467
pharmacy intern to dispense naloxone without a prescription in	468

includes in the database pursuant to rules adopted under section

The board also shall use the drug database to monitor

4729.84 of the Revised Code. In

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<pre>naltrexone.</pre>	498
<u>In</u> establishing and maintaining the database, the board	499
shall electronically collect information pursuant to sections	500
4729.77, 4729.771, 4729.772, 4729.78, and 4729.79 of the Revised	501
Code and shall disseminate information as authorized or required	502
by sections 4729.80 and 4729.81 of the Revised Code. The board's	503
collection and dissemination of information shall be conducted	504
in accordance with rules adopted under section 4729.84 of the	505
Revised Code.	506
Sec. 4729.79. (A) If the state board of pharmacy	507
establishes and maintains a drug database pursuant to section	508
4729.75 of the Revised Code, each licensed health professional	509
authorized to prescribe drugs, except as provided in division	510
(C) of this section, who personally furnishes to a patient a	511
controlled substance, naltrexone, or other dangerous drug the	512
board includes in the database pursuant to rules adopted under	513
section 4729.84 of the Revised Code shall submit to the board	514
the following information:	515
(1) Prescriber identification;	516
(2) Patient identification;	517
(3) Date drug was furnished by the prescriber;	518
(4) Indication of whether the drug furnished is new or a	519
refill;	520
(5) Name, strength, and national drug code of drug	521
furnished;	522
(6) Quantity of drug furnished;	523
(7) Number of days' supply of drug furnished;	524

(8) Source of payment for the drug furnished;	525
(9) Identification of the owner of the drug furnished.	526
(B)(1) The information shall be transmitted as specified	527
by the board in rules adopted under section 4729.84 of the	528
Revised Code.	529
(2) The information shall be submitted electronically in	530
the format specified by the board, except that the board may	531
grant a waiver allowing the prescriber to submit the information	532
in another format.	533
(3) The information shall be submitted in accordance with	534
any time limits specified by the board, except that the board	535
may grant an extension if either of the following occurs:	536
(a) The prescriber's transmission system suffers a	537
mechanical or electronic failure, or the prescriber cannot meet	538
the deadline for other reasons beyond the prescriber's control.	539
(b) The board is unable to receive electronic submissions.	540
(C)(1) The information required to be submitted under	541
division (A) of this section may be submitted on behalf of the	542
prescriber by the owner of the drug being personally furnished	543
or by a delegate approved by that owner.	544
(2) The requirements of this section to submit information	545
to the board do not apply to a prescriber who is a veterinarian.	546
(D) If the board becomes aware of a prescriber's failure	547
to comply with this section, the board shall notify the	548
government entity responsible for licensing the prescriber.	549
Sec. 4729.85. If the state board of pharmacy establishes	550
and maintains a drug database nursuant to section 4729 75 of the	551

Revised Code, the board shall prepare reports regarding the	552
database and present or submit them in accordance with both of	553
the following:	554
(A) The board shall present a biennial report to the	555
standing committees of the house of representatives and the	556
senate that are primarily responsible for considering health and	557
human services issues. Each report shall include all of the	558
following:	559
(1) The cost to the state of establishing and maintaining	560
the database;	561
(2) Information from the board, terminal distributors of	562
dangerous drugs, prescribers, and retail dispensaries licensed	563
under Chapter 3796. of the Revised Code regarding the board's	564
effectiveness in providing information from the database;	565
(3) The board's timeliness in transmitting information	566
from the database.	567
(B) The board shall submit a semiannual report to the	568
governor, the president of the senate, the speaker of the house	569
of representatives, the attorney general, the chairpersons of	570
the standing committees of the house of representatives and the	571
senate that are primarily responsible for considering health and	572
human services issues, the department of public safety, the	573
state dental board, the board of nursing, the state vision	574
professionals board, the state medical board, and the state	575
veterinary medical licensing board. The state board of pharmacy	576
shall make the report available to the public on its internet	577
web site. Each report submitted shall include all of the	578
following for the period covered by the report:	579
(1) An aggregate of the information submitted to the board	580

(4) An aggregate of the information submitted to the board	608
under sections 4729.77 and 4729.79 of the Revised Code regarding	609
naltrexone, including all of the following:	610
(a) The number of prescribers who issued the prescriptions	611
for or personally furnished the drug;	612
(b) The number of patients to whom the drug was dispensed	613
or personally furnished;	614
(c) The average quantity of the drug dispensed per	615
prescription or furnished at one time.	616
Sec. 4730.56. (A) As used in this section:	617
(1) "Community addiction services provider" has the same	618
meaning as in section 5119.01 of the Revised Code.	619
(2) "Medication-assisted treatment" has the same meaning	620
as in section 340.01 of the Revised Code.	621
(B) A physician assistant shall comply with section	622
3715.08 3719.064 of the Revised Code and rules adopted under	623
section 4730.55 of the Revised Code when treating a patient with	624
medication-assisted treatment or proposing to initiate such	625
treatment.	626
(C) A physician assistant who fails to comply with this	627
section shall treat not more than thirty patients at any one	628
time with medication-assisted treatment even if the facility or	629
location at which the treatment is provided is either of the	630
following:	631
(1) Exempted by divisions (B)(2)(a) to (d) of section	632
4729.553 of the Revised Code from being required to possess a	633
category III terminal distributor of dangerous drugs license	634
with an office-based opioid treatment classification;	635

collects any of the following information regarding the

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administration of naloxone by emergency medical service	664
personnel or any firefighter or volunteer firefighter, the	665
department of public safety shall report the information for the	666
previous month to the department of health on a monthly basis	667
and in a manner prescribed by the department of health:	668
(1) The five-digit postal zip code plus four-digit add-on	669
where the naloxone was administered;	670
(2) The date on which the naloxone was administered;	671
(3) The number of doses administered;	672
(4) The name of the emergency medical service organization	673
or fire department that administered the naloxone;	674
(5) Whether or not an overdose was reversed;	675
(6) Whether the individual to whom naloxone was	676
administered was taken to a hospital;	677
(7) If known, the individual's age;	678
(8) If known, the United States postal zip code in which	679
the individual resides.	680
When reporting to the department of health, the department	681
of public safety shall not include any information that	682
identifies or tends to identify specific individuals to whom	683
<pre>naloxone was administered.</pre>	684
(B) Each month, the department of health shall compile the	685
information received under division (A) of this section,	686
organize it by county, and forward it to each board of alcohol,	687
drug addiction, and mental health services in this state.	688
(C) The department of health may adopt rules as necessary	689
to implement this section. The rules shall be adopted in	690

accordance with Chapter 119. of the Revised Code. 691 Sec. 5119.363. The director of mental health and addiction 692 services shall adopt rules governing the duties of boards of 693 alcohol, drug addiction, and mental health services under 694 section 340.20 of the Revised Code and the duties of community 695 addiction services providers under section 5119.362 of the 696 Revised Code. The rules shall be adopted in accordance with 697 Chapter 119. of the Revised Code. 698 The director shall adopt rules under this section that 699 authorize the department of mental health and addiction services 700 to determine an advanced practice registered nurse's, physician 701 assistant's, or physician's compliance with section 3715.08 702 3719.064 of the Revised Code if such practitioner works for a 703 community addiction services provider. 704 Section 2. That existing section 3715.08, 4723.52, 705 4729.01, 4729.44, 4729.75, 4729.79, 4729.85, 4730.56, 4731.83, 706 and 5119.363 of the Revised Code are hereby repealed. 707 Section 3. Sections 3715.08, 3719.063, 3719.064, 4723.52, 708 4729.283, 4730.56, 4731.83, and 5119.63 of the Revised Code, as 709 amended or enacted by this act, shall be known as "Daniel's 710 Law." 711 Sections 4729.01, 4729.44, 4729.75, 4729.79, 4729.85, and 712 4765.45 of the Revised Code, as amended or enacted by this act, 713 shall be known as the "Opioid Data and Communication Expansion 714 Act." 715